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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,970	01/13/2004	Kevin T. Foley	4002-3443/PC444.06	3770

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EXAMINER	
HOFFMAN, MARY C	

ART UNIT	PAPER NUMBER
3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/756,970	FOLEY ET AL.	
	Examiner	Art Unit	
	Mary Hoffman	3733	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-93* is/are pending in the application.

4a) Of the above claim(s) *71-73 and 80-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-70 and 74-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/06,2/4/05,1/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, Species A, Figs 1-6, claims 54-70 and 74-79, in the reply filed on 02/21/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 71-73 and 80-93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/21/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-70 and 75-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Brazier (U.S. Patent No. 4,995,686).

Brazier discloses instrumentation comprising an elongate member (FIG. 2) extending along a longitudinal axis and including a deformable distal portion (ref. #20) having an initial configuration and an expanded configuration wherein the deformable

distal portion is outwardly deformed to define at least one transverse projection, the at least one transverse projection arranged along a single transverse axis such that at least a portion of the spinal structure is uniaxially displaced along the transverse axis. Displacement of the at least a portion of the spinal structure is can be directionally controlled. Displacement of the at least a portion of the spinal structure is can be unidirectional. Outward deformation of the at least one transverse projection is selectively controlled to generate a controlled magnitude of force against a body structure, such as a spinal structure. The expanded configuration defines a pair of the transverse projections arranged generally opposite one another along the transverse axis. The elongate member comprises an inner actuator member (ref. #10) disposed within an outer sleeve member (ref. #12), a distal portion of the sleeve member being outwardly deformed to define the at least one transverse projection in response to relative displacement between the actuator member and the sleeve member. The relative displacement between the actuator member and the sleeve member is relative linear displacement. The relative displacement between the actuator member and the sleeve member is regulated to generate a controlled magnitude of force. The instrumentation further comprises an actuator mechanism (ref. #16/44) coupled between the actuator member and the sleeve member and being operable to impart the relative displacement therebetween. The actuator mechanism comprises a first portion coupled to the actuator member; and a second portion coupled to the sleeve member and engaged with the first portion; wherein relative rotation between the first and second portions imparts relative linear displacement between the actuator member and

the sleeve member to cause the distal portion of the sleeve member to reform from the initial configuration toward the expanded configuration. The deformable distal portion comprises at least one flexible strip of material, the flexible strip of material having an outwardly buckled configuration defining the at least one transverse projection. The deformable distal portion comprises a pair of the flexible strips of material disposed generally opposite one another, the pair of flexible strips of material defining a pair of transverse projections disposed generally opposite one another when transitioned to the outwardly buckled configuration. The flexible strip of material has a predetermined shape to provide controlled transitioning to the outwardly buckled configuration. The predetermined shape includes a series of arcuate portions. The deformable distal portion defines a plurality of slots (ref. #21), the slots facilitating outward buckling of the deformable distal portion to define the at least one transverse projection. Each of the plurality of slots has a predetermined shape to provide controlled outward buckling. The predetermined shape is at least partially comprised of an hour-glass shape.

Claims 54-70 and 75-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti (U.S. Patent No. 5,454,365).

Bonutti discloses instrumentation comprising an elongate member (FIG. 2) extending along a longitudinal axis and including a deformable distal portion (ref. #60) having an initial configuration and an expanded configuration wherein the deformable distal portion is outwardly deformed to define at least one transverse projection, the at least one transverse projection arranged along a single transverse axis such that at least a portion of the spinal structure is uniaxially displaced along the transverse axis.

Displacement of the at least a portion of the spinal structure is can be directionally controlled. Displacement of the at least a portion of the spinal structure is can be unidirectional. Outward deformation of the at least one transverse projection is selectively controlled to generate a controlled magnitude of force against a body structure, such as a spinal structure. The expanded configuration defines a pair of the transverse projections arranged generally opposite one another along the transverse axis. The elongate member comprises an inner actuator member (ref. #18) disposed within an outer sleeve member (ref. #40), a distal portion of the sleeve member being outwardly deformed to define the at least one transverse projection in response to relative displacement between the actuator member and the sleeve member. The relative displacement between the actuator member and the sleeve member is relative linear displacement. The relative displacement between the actuator member and the sleeve member is regulated to generate a controlled magnitude of force. The instrumentation further comprises an actuator mechanism (ref. #22/16) coupled between the actuator member and the sleeve member and being operable to impart the relative displacement therebetween. The actuator mechanism comprises a first portion coupled to the actuator member; and a second portion coupled to the sleeve member and engaged with the first portion; wherein relative rotation between the first and second portions imparts relative linear displacement between the actuator member and the sleeve member to cause the distal portion of the sleeve member to reform from the initial configuration toward the expanded configuration. The deformable distal portion comprises at least one flexible strip of material, the flexible strip of material having an

outwardly buckled configuration defining the at least one transverse projection. The deformable distal portion comprises a pair of the flexible strips of material disposed generally opposite one another, the pair of flexible strips of material defining a pair of transverse projections disposed generally opposite one another when transitioned to the outwardly buckled configuration. The flexible strip of material has a predetermined shape to provide controlled transitioning to the outwardly buckled configuration. The predetermined shape includes a series of arcuate portions. The deformable distal portion defines a plurality of slots (ref. #68/62), the slots facilitating outward buckling of the deformable distal portion to define the at least one transverse projection. Each of the plurality of slots has a predetermined shape to provide controlled outward buckling. The predetermined shape is at least partially comprised of an hour-glass shape.

Claims 54-58 and 64-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Sachdeva et al. (U.S. Patent No. 5,885,258).

Sachdeva et al. instrumentation comprising an elongate member (FIG. 3) extending along a longitudinal axis and including a deformable distal portion (ref. #32) having an initial configuration and an expanded configuration wherein the deformable distal portion is outwardly deformed to define at least one transverse projection, the at least one transverse projection arranged along a single transverse axis such that at least a portion of the spinal structure can be uniaxially displaced along the transverse axis. Displacement of the at least a portion of the spinal structure is directionally controlled. Displacement of the at least a portion of the spinal structure is unidirectional. Outward deformation of the at least one transverse projection is selectively controlled to

generate a controlled magnitude of force against the at least a portion of the spinal structure. The expanded configuration defines a pair of the transverse projections arranged generally opposite one another along the transverse axis. The deformable distal portion comprises at least one flexible strip of material, the flexible strip of material having an outwardly buckled configuration defining the at least one transverse projection. The deformable distal portion comprises a pair of the flexible strips of material disposed generally opposite one another, the pair of flexible strips of material defining a pair of transverse projections disposed generally opposite one another when transitioned to the outwardly buckled configuration. The flexible strip of material has a predetermined shape to provide controlled transitioning to the outwardly buckled configuration. The predetermined shape includes a series of arcuate portions. The deformable distal portion defines a plurality of slots, the slots facilitating outward buckling of the deformable distal portion to define the at least one transverse projection. Each of the plurality of slots has a predetermined shape to provide controlled outward buckling. The predetermined shape is at least partially comprised of an hour-glass shape. The deformable distal portion is at least partially formed of a shape-memory material, the deformable distal portion being reformed from the initial configuration toward the expanded configuration in response to the imposition of stress and automatically reformed back toward the initial configuration upon removal of the stress.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brazier (U.S. Patent No. 4,995,686).

Brazier discloses the claimed invention except for the deformable distal portion being at least partially formed of a shape-memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the deformable distal portion of Brazier at least partially formed of a shape-memory material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (U.S. Patent No. 5,454,365).

Bonutti discloses the claimed invention except for the deformable distal portion being at least partially formed of a shape-memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the deformable distal portion of Bonutti at least partially formed of a shape-memory material, since it has been held to be within the general skill of a worker in the art to

select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 54 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,676,665. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite the same structural limitations and encompass the same scope.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER